EPA/OPP MICROBIOLOGY LABORATORY
ESC, Ft. Meade, MD

Standard Operating Procedure
for
Operations of the Quality Assurance Unit

SOP QA-01-02

Date Revised: 08-28-02

Prepared By: _____Date:___/___/___

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Reviewed By:_____ Date: ___/___/___

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OPP Quality Assurance Manager

Date Issued: _____/_____/_____

Withdrawn By: _____ Date: ___/___/____

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1.0 SCOPE AND APPLICATION:

1.1 The purpose of this SOP is to describe the operations of the Quality Assurance Unit (QAU). The Quality Assurance Manager (QAM) for the Office of Pesticide Programs (OPP), or their designated agent, and the Quality Assurance Officer (QAO) and alternate QAO, Office of Pesticide Programs (OPP), Biological and Economic Analysis Division (BEAD), Antimicrobials and Plant Pathogens Branch (APPB) shall function as the QAU. This unit is responsible for monitoring studies, including disinfectant efficacy testing and related activities, carried out at the OPP Microbiology Laboratory located in the Environmental Science Center (ESC) at Fort Meade, Maryland (see ref. 15.6).

1.2 The QAU shall comply with the EPA Good Laboratory Practice Standards (GLPs), and adhere to guidance stipulated in the OPP Microbiology Laboratory Quality Management Plan, and the overall OPP Quality Assurance Management Plan. The QAO is responsible for developing the Quality Management Plan for the OPP Microbiology Laboratory. Objectives are to ensure that the facilities, equipment, personnel, methods, practices, records and controls conform to these requirements in the plan.

1.3 The QAU shall function or act independently of personnel engaged in the direction and conduct of the laboratory procedures and studies under review. The QAU conducts audits of and monitors laboratory activities to ensure compliance with GLPs. The Laboratory Director is responsible for coordination of GLP and technical audits performed by external parties. The QAM is responsible for coordinating quality management systems reviews.

2.0 DEFINITIONS:

2.1 QAO = Quality Assurance Officer, Antimicrobials and Plant Pathogens Branch (APPB).

2.2 QAM = Quality Assurance Manager, Office of Pesticide Programs (OPP).

2.3 Laboratory = OPP Microbiology Laboratory located in the Environmental Science Center, Fort Meade, Maryland.

2.4 Team Leader = the team leader for the group of OPP analysts located at

the Laboratory.

2.5 Laboratory Director = Branch Chief, Antimicrobials and Plant Pathogens Branch (APPB)

2.6 GLP = Good Laboratory Practices (EPA GLPs are codified in 40CFR Part 160)

3.0 HEALTH AND SAFETY: Not applicable

4.0 CAUTIONS: None

5.0 INTERFERENCES: None

6.0 PERSONNEL QUALIFICATIONS:

6.1 The QAO and alternate shall complete the Agency's basic quality assurance course "Introduction to EPA Quality Systems." Continuing education is recommended by participating in the EPA Annual National Conference on Managing Environmental Quality Systems, and by attending additional workshops or courses offered by the EPA Office of Environmental Information Quality Staff or other organizations that may offer such training.

7.0 APPARATUS AND MATERIALS: None

8.0 INSTRUMENT OR METHOD CALIBRATION: Not applicable

9.0 SAMPLE HANDLING AND STORAGE: Not applicable

10.0 PROCEDURE AND ANALYSIS:

10.1 Summary: The APPB QAO, or the designated alternate, has responsibility for observing and auditing the on-site operations of the laboratory. The QAO reports directly to the OPP Quality Assurance Manager (QAM), on QA matters, but otherwise reports directly to the APPB Branch Chief. A system for reviewing and issuing SOPs shall be maintained to ensure that methods and practices are properly documented.

The QAU shall monitor operations through audits of laboratory systems

and methods. All final data reports shall be reviewed to assure that the results agree with the raw data and the methods and SOPs which were used are correctly described. Files of master copies of all SOPs, QA records of audits, analyst's quality assurance training, and other Quality Assurance records shall be maintained in the OPP Laboratory Archives.

10.2 Conformance to GLPs: The QAU shall operate in compliance with GLPs . Specific responsibilities of the QAU are included in Section 160.35 ("Quality Assurance Unit") of 40CFR, "Good Laboratory Practice Standards."

10.2.1 Master Schedule: The QAU shall maintain a copy of the master schedule of all studies conducted by the laboratory. The schedule shall include: test substance, test system, nature of study, initiation date, status, sponsor and study director. The efficacy testing of disinfectants is an ongoing activity, supported by Agency recognized methods and procedures. These methods and procedures are described in the SOPs that support these tests. The schedules of testing activities will be developed by the Laboratory Director in conjunction with the laboratory Team Leader. The QAU will maintain copies of these schedules. These schedules will be used to develop test study auditing schedules.

10.2.2 Protocols: The QAU will maintain copies of all SOPs and protocols for all studies the QAU has responsibility to monitor. The efficacy testing SOPs describe the steps involved in efficacy evaluations and general laboratory operations. A file will be maintained with the QAU records. SOP ADM-03, Records and Archives, provides directions for maintenance of all records. The study protocol shall contain, but shall not necessarily be limited to, the following: a descriptive title and statement of the purpose of the study; identification of test, control and reference substances; name and address of sponsor, if applicable, and of testing facility; proposed experimental start and termination dates; justification for test system; records to be maintained; the procedure for ID of the test system; description of experimental design; date of approval of the protocol by the

sponsor or study director and the dated signature of the study director; statement of any proposed statistical method(s) to be used; and changes or revisions of an approved protocol and the reasons therefore with the dated signature of the study director.

10.2.3 Training Files: The Laboratory shall maintain a current summary of training and experience for each individual involved in the supervision or conduct of a study. These files shall contain, but not necessarily be limited to, the following: curriculum vitae, job descriptions, training certifications, and courses and seminars taken.

10.2.4 Audits: Selected studies will be audited at intervals to ensure the integrity of the studies. Written records of each audit which show the following information: names and signatures of auditors, date of audit, title of function audited, scope of audit, findings, actions recommended and taken to resolve issues, and schedule for any follow-up audit. The procedure for audits performed by the QAU is described in SOP QA-02, Internal Quality Assurance Audits. Essentially each item in the GLPs pertaining to responsibility of the QAU is addressed in the SOP.

10.2.5 Reports: The QAO will prepare periodic written reports to management and the study director on the status of each study, noting any problems and actions taken to eliminate the problems. All study reports are reviewed by the QAO and findings are reported to the Team Leader and a copy is sent to the Laboratory Director. Likewise, results of annual systems and methods audits are sent to the Team Leader with a copy sent to the Laboratory Director. The Team Leader is responsible for sending to the QAO a follow-up report addressing findings and corrective actions taken where necessary.

10.2.6 Findings: The QAO shall determine that no deviations from approved protocols and SOPs were made without proper authorization and documentation. The QAU shall audit the

performance of all methods to ensure that all methods are followed as written. All deviations from approved protocols or SOPs must be approved and documented by the Team Leader. All major revisions of SOPs shall follow SOP ADM-02, Preparation of SOPs, which describes the procedure, organization, and format of SOPS, their review and approval, revision, and storage. If a deviation is made that will require a change in the SOP, such as a permanent change in incubation time, the Team Leader shall initiate an addendum to the SOP. The addendum is circulated for review and approval by the QAO. Once the addendum is approved, the QAO shall distribute controlled copies which are appended to the existing SOPs. The addendum shall be filed with the appropriate SOP in the QAO's controlled copy of the current SOPs, and verified at the next audit. The addendum shall be incorporated into the SOP during the annual SOP revision process.

10.2.7 Final Reports. The QAU will review the final study report to assure that the report accurately describes methods and SOPs and the reported results accurately reflect raw data for the study. The QAO shall provide a final review of disinfectant performance reports and data. These data shall be compiled by the analysts according to the SOP which describes the contents of disinfectant report packages (SOP ADM-01, Preparation of Performance Reports). The study final report shall include but, not necessarily be limited to: name and address of the facility performing the study and the dates on which the study was initiated, completed, terminated, or discontinued; objectives and procedures stated in the approved protocol; statistical method(s) employed; test, control, and reference substances; method used; any circumstances that may have affected the quality or integrity of the data; the names of the study director and all other personnel involved in the study; signature and date of signature of each person involved in the study; locations where samples, raw data and final report will be stored; and a signed statement of review by the quality assurance unit. The final report and GLP compliance statement shall be signed and dated by the study director. Corrections or

additions shall be in the form of amendments by the study director. Compliance with GLPs, or any deviation therefrom, in the conduct of the study will be evaluated by the QAO or alternate QAO. A copy of the final report and any amendment to it shall be maintained by the sponsor, if applicable, and the test facility.

10.2.8 Authorization: The QAO or alternate QAO will prepare and sign a statement included with the data report which specifies the audit dates and findings reported to management and the study director.

10.2.9 Records: The QAU shall maintain in writing the following: QAU responsibilities, procedures, records maintained and indexing procedures. These documents and files shall be made available to authorized EPA employees and/or their representatives. The QAU shall prepare documentation of responsibilities and procedures. This SOP was written to fulfill that requirement. SOP ADM-03, Records and Archives, describes quality assurance file maintenance which complies with the Agency's official records retention schedules. All QAU files shall be available to authorized EPA employees and/or their representatives.

11.0 DATA ANALYSIS/CALCULATIONS: None

12.0 DATA MANAGEMENT/RECORDS MANAGEMENT:

12.1 Results of reviews of data and reports, findings from audits, and any other documentation of quality assurance activities, including quality assurance records required by GLPs, will be filed in the QAU's files located in Room D217 EPA Environmental Science Center, Fort Meade, Maryland 20755-5350. These documents are subject to OPP's records retention schedule contained in SOP ADM-03, Records and Archives.

13.0 QUALITY CONTROL/QUALITY ASSURANCE:

13.1 The OPP Microbiology Laboratory complies with 40 CFR Part 160, Good Laboratory Practices. Appropriate quality control measures are integrated

into each SOP.

14.0 NONCONFORMANCE AND CORRECTIVE ACTION:

14.1 Any nonconformance will be corrected upon discovery.

15.0 REFERENCES:

15.1 EPA Good Laboratory Practice Standards, 40CFR Part 160.

16.0 FORMS AND DATA SHEETS: None